

(12) UK Patent Application (19) GB (11) 2 296 663 (13) A

(43) Date of A Publication 10.07.1996

(21) Application No 9500008.9

(22) Date of Filing 03.01.1995

(71) Applicant(s)
Ahmed Salih Mahmud
13 Holyrood Close, Spondon, Derby, DE2 7QB,
United Kingdom

(72) Inventor(s)
Ahmed Salih Mahmud

(74) Agent and/or Address for Service
John Raymond Badger
6 Simpson Road, Wyde Green, SUTTON COLDFIELD,
West Midlands, B72 1EP, United Kingdom

(51) INT CL⁶
A61F 9/007

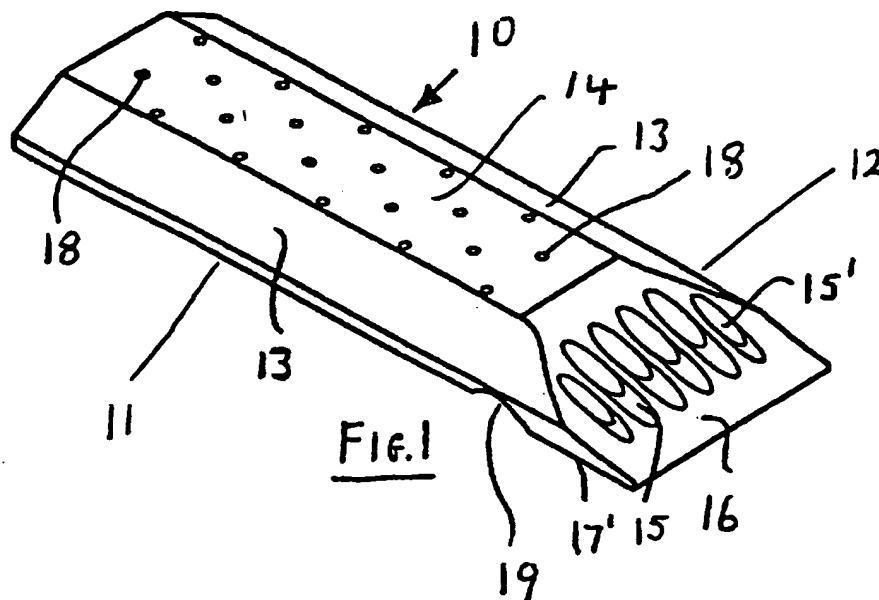
(52) UK CL (Edition O)
A5R RCEX
U1S S1029

(56) Documents Cited
WO 94/02081 A1 WO 91/18568 A1 WO 91/12046 A1
US 5300020 A US 5034176 A US 4037604 A
US 3788327 A

(58) Field of Search
UK CL (Edition O) A5R RCEX RGE B RGEX RGH
INT CL⁶ A61F 9/00

(54) Drainage device for alleviating excess ophthalmic fluid pressure

(57) Ophthalmic drainage device 10 comprises an elongate, transparent body of polymeric material having a relatively flexible scleral portion 11 and a relatively stiffened, tapered anterior portion 12. The body contains a plurality of longitudinal passages 15, 15' and has a groove 19 that assists in retention of the device 10. In use, the device 10 is inserted into the anterior chamber of the eye through an incision in the sclera allowing fluid to pass through passages 15, 15' and out of the rear of the device through their exposed ends. Fluid also passes out through auxiliary drainage holes 18. Also described is a method of using the above device and an insertion tool comprising a pair of adapted forceps (40).



GB 2 296 663 A

1/2

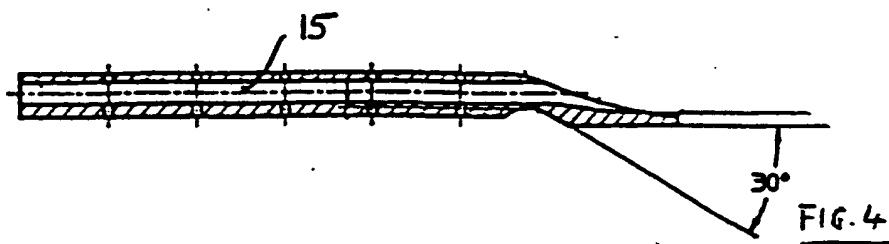
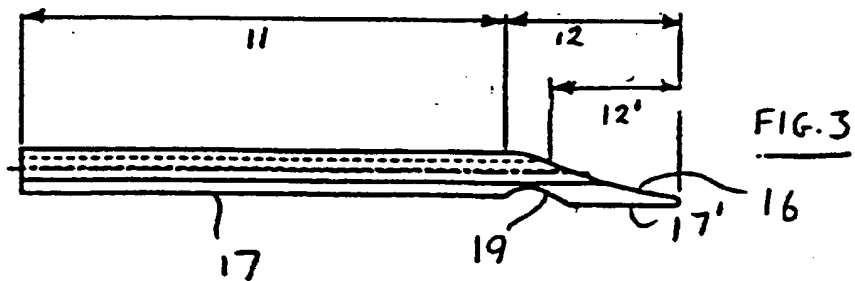
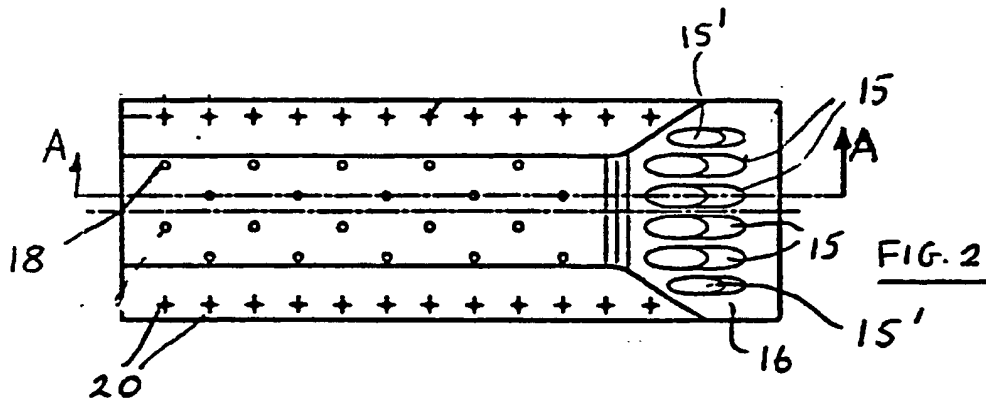
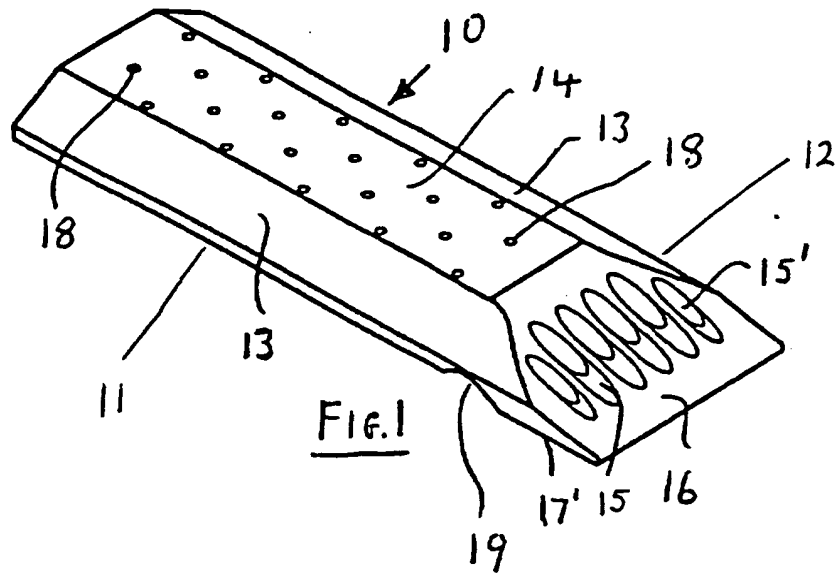


FIG. 5

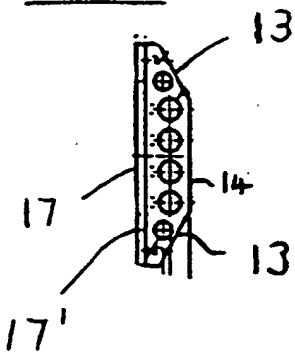


FIG. 8

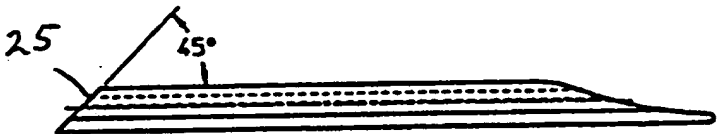
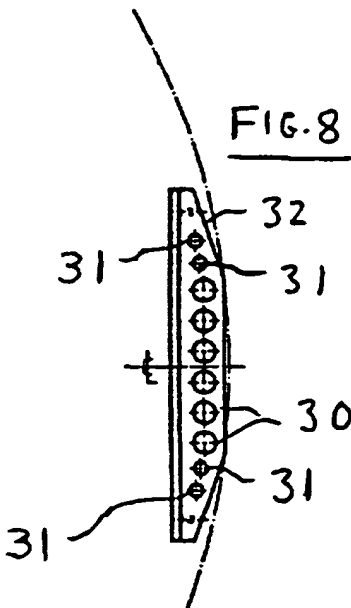


FIG. 6

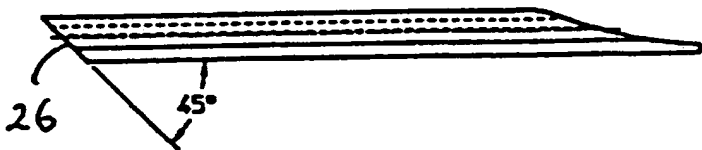


FIG. 7

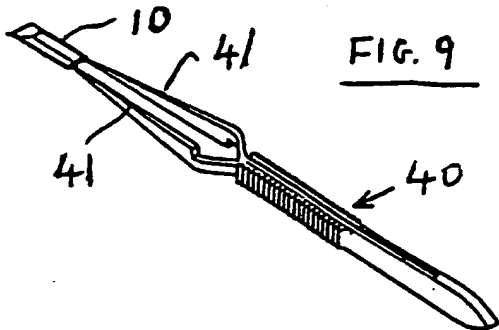


FIG. 9

OPHTHALMIC DRAINAGE DEVICE

This invention relates to an ophthalmic drainage device and in particular, though not exclusively, to an ophthalmic drainage device of a micro tubular type and suitable for use in eye surgery, e.g. in a glaucoma or other drainage operation.

The invention provides also support means for and a method of use of the drainage device of the invention.

In the treatment of conditions such as glaucoma procedures are well established for the relief of high fluid pressure in the eye. Often these procedures are successful, but there is ever present a risk of complications the correction of which can be difficult and time-consuming.

The present invention seeks to provide a means for and method of relief of high fluid pressure which mitigates or eliminates at least some of the risks associated with the presently known and well established procedures.

In accordance with one of its aspects the present invention provides an ophthalmic drainage device comprising an elongate body of flexible polymeric material shaped to define a passage zone which extends lengthwise through the body, the body comprising a scleral portion and an anterior chamber portion respectively for location in the scleral and anterior chamber portions of an eye, the end region of the body of said anterior chamber portion being tapered in thickness to reduce in thickness in a direction from the scleral portion to the end of the anterior chamber portion.

The invention is not limited to a passage zone of any specific transverse cross-sectional shape, and envisages that the transverse cross-sectional shape of the elongate passage typically will have a width to thickness ratio of at least 1.50, more typically at least 5.0. The tapered end region may be arranged to taper in thickness, as considered along its length, in a direction which corresponds to the thickness direction of the passage zone.

Optionally the anterior chamber portion may be tapered over at least 50% or even over at least 75% of the length of that portion, but it is to be understood that the tapered portion may be of a shorter length. The taper

may be uniform in shape, as considered in a longitudinal cross-sectional plane, or may be steeper where it intersects the passage zone at a position at one or both sides of that zone. Preferably the passage zone terminates at a surface which intersects the passage zone obliquely.

The transition from the scleral portion to the anterior chamber portion may be at a position at which the transverse cross-sectional shape of the body changes. It may be at a position at which the taper of the anterior chamber commences.

It is envisaged that usually the scleral portion will be of a constant cross-sectional shape and dimension along substantially the whole of its length, but the invention does not exclude provision of a scleral portion of varying cross-sectional shape or size.

The passage zone may comprise a single passageway, in which case it is envisaged that typically it will be of a non-circular cross-sectional shape. Alternatively the passage zone may comprise a plurality of discrete passages which extend lengthwise through the body and are substantially parallel with one another. The passages of a plurality may be positioned to lie in a substantially co-planar manner.

The or each passage may be of a uniform cross-section along substantially the whole of the length thereof. If the passage zone comprises a plurality of discrete passages, all of the passages may be of the same cross-sectional size or shape.

It is further envisaged that the or each drainage passage preferably has a cross-sectional area less than 1.0 sq. mm, more preferably less than 0.5 sq. mm. In the case of a passage of circular cross-sectional shape the diameter of the passage typically will be less than 1.0 mm, more typically less than 0.8 mm.

The or each passage may extend rectilinearly between ends of the elongate body or it may be non-rectilinear. It may, for example, be of a zig-zag form whereby it may provide a greater flow resistance and better absorb any sudden increase of intra-ocular pressure.

Side regions extending lengthwise along the edges of the body of

polymeric material also may be tapered, in this case as considered in a plane transverse to the length of the body.

Side regions of the body, whether tapered or not, may be provided with suture holes.

Particularly but not necessarily only in the case of a body having tapered side regions, if the passage zone comprises a plurality of discrete passages some of those passages, particularly those closest to side regions, may be of a smaller size than other passages of the plurality, or of a different cross-sectional shape.

An outer surface region of the body may be perforated to provide auxiliary drainage holes which communicate with said passage zone. Auxiliary drainage holes may be in the form of auxiliary passages which extend substantially perpendicular to and communicate with a drainage passage of the passage zone.

The drainage holes preferably each have a cross-sectional area which is less than one half, more preferably a quarter or less than, the cross-sectional area of the drainage passage with which they communicate.

Outer surface regions of the body may be smooth, or some or all of those regions may be textured.

The passage zone may be of a kind which permits substantially unrestricted flow of fluid therethrough, at least in a direction from the anterior chamber portion to the scleral portion. The passage or at least some of a plurality of passages of a passage zone may incorporate valve means such as a one-way valve arranged to prevent or restrict reverse flow in a direction from the scleral to the anterior chamber portion and thereby, for example, assist in further reducing the risk of infection.

The tapered end region of the anterior chamber portion of the body preferably comprises one or a pair of outer surfaces which extend(s) across the width of the elongate body in the same direction as a width direction of the passage zone. One or both of these surfaces may lie obliquely relative to the lengthwise direction of the passage zone, and may intersect the passage zone. One or both of said surfaces may lie at least in part parallel

with the lengthwise direction of the passage zone.

The scleral portion may comprise a base portion surface which is substantially planar and has a width at least equal to that of the passage zone.

The anterior chamber portion may comprise a base portion surface which is co-planar with said base portion surface of the scleral portion.

Alternatively, the anterior chamber portion may be provided with an extension zone such that a base portion surface of the anterior chamber portion is displaced to lie further from the passage zone and thereby be able to act as an iris depressor and assist in avoiding iris block or contact with the corneal endothelium.

A transverse formation such as a groove may be provided between the anterior chamber and scleral portions to assist in retaining the drainage device in position, e.g. when inserted in a scleral tunnel.

The distal end of the anterior chamber portion may be rectilinear or of another shape, such as of fluted or wavy form.

The material of the flexible elongate body may be of non-uniform physical properties. The material may be stiffer and/or less resilient at the anterior chamber portion than the scleral portion, or at least a distal end of the anterior chamber portion may be stiffer. It may thereby be provided that the anterior chamber portion or at least the distal end thereof is adequately resistant to bending, especially bending which might otherwise occur during use, e.g. during insertion into a scleral tunnel.

The material may be transparent.

The flexible elongate body may incorporate reinforcing material and that reinforcement may be selectively positioned to provide the aforementioned resistance to bending.

The invention provides in accordance with another of its aspects support means for assisting in use of the drainage device of the invention, said support means comprising forceps having a pair of substantially rectilinear arms which are blunt ended and each have a diameter of less than 1.0 mm, preferably less than 0.5 mm whereby said arms may be inserted into

the passage zone of the drainage device to provide support and allow position control during insertion.

The invention further provides a method for ophthalmic drainage comprising creating a scleral tunnel by making a phaco incision, advancing a knife towards the limbus and just into clear cornea to form a scleral tunnel which extends to just above the iris root, conducting paracentesis, inserting into the scleral tunnel a drainage device in accordance with the present invention, and securing the drainage device to the sclera.

Optionally the then exposed end of the drainage device may be cut to lie close to the edge of the incision.

Embodiments of the present invention will now be described, by way of example only, with reference to the accompanying diagrammatical drawings in which:-

Figure 1 is a perspective view of a drainage device in accordance with the present invention;

Figure 2 is a plan view of the device of Figure 1;

Figure 3 is a side view of the device of Figure 1;

Figure 4 is a section on the line A-A of Figure 2;

Figure 5 is an end view of the device of Figure 1;

Figures 6 and 7 are side views of drainage devices in accordance with other embodiments of the invention;

Figure 8 is an end view of a drainage device in accordance with a further embodiment of the invention; and

Figure 9 is a perspective view of a support tool for use with the devices of Figures 1 to 8.

An ophthalmic drainage device 10 comprises an elongate body of a flexible polymeric material of a quality suitable for implant use.

The body in the embodiment has a length of 15 mm, a width of 4.3 mm and an overall thickness of 1.2 mm.

A major part of the length of the device is comprised by a scleral portion 11 for location in the scleral portion of an eye. The remainder of the length is comprised by an anterior chamber portion 12 which is of tapered

shape over a major part of its length as viewed in Figure 3.

The scleral portion 11 is of a generally rectangular shape in transverse cross-section apart from two bevelled side regions 13 (see Figure 5) which lie either side of an upper face region 14.

An array of six substantially co-planar drainage passages 15, 15' extends lengthwise through the body and an end of each intersects with a tapered surface 16 at the anterior chamber portion. Four of the passages 15 are of the same circular cross-sectional size, in this case 0.50 mm diameter and lie centrally between two edge passages 15' that are positioned under the bevelled side edges 13 and have a smaller circular cross-sectional size, in this case 0.40 mm.

The upper surface 14 and a base portion surface 17 are provided with auxiliary drainage holes 18 that extend perpendicular to and communicate with the central passages 15. The drainage holes 18 are of a smaller size than the passages 15, and have a diameter of 0.2 mm.

A transverse groove 19 is provided in the base portion surface to assist in location of the drainage device when implanted. In addition the longitudinal side regions are provided with suture holes 20.

An end region 12' of the anterior chamber portion has a base surface zone 17' which lies further from the plane of the passages 15, 15' than the base surface in the scleral portion. That end region 12' serves in use as an iris depressor.

The end of the device in the scleral portion is square cut as shown in Figure 3 but alternatively may be angled to have a transverse face 25, 26 inclined in either of two directions as shown respectively in Figures 6 and 7.

A further alternative construction is shown in Figure 8 and comprises six central drainage passages 30 and four side passages 31 arranged in pairs under the respective bevelled sides 32.

In the construction of Figures 1 to 5 the passages 15, 15' form a passageway zone which has a transverse width of approximately 3.76 mm and a thickness of 0.5 mm, resulting in a width to thickness ratio of approximately 7.5. In contrast, in the Figure 8 construction the width of the

passage zone is approximately 8.0 mm, resulting in a width to thickness ratio of approximately 16.0.

Figure 9 shows a pair of forceps 40 which are suitable for supporting the drainage devices of Figures 1 to 8 during an implant procedure. The forceps 40 comprise a pair of substantially parallel arms 41 the ends of which (shown extending into a device 10) are of a diameter of 0.45 mm and are blunt ended. The arms therefore are able to fit into a pair, e.g. an outer pair, of the central drainage passages 15 to support the device against bending during insertion into a scleral tunnel and to assist in locating the drainage device in the required position.

CLAIMS:

1. An ophthalmic drainage device comprising an elongate body of flexible polymeric material shaped to define a passage zone which extends lengthwise through the body, the body comprising a scleral portion and an anterior chamber portion respectively for location in the scleral and anterior chamber portions of an eye, the end region of the body of said anterior chamber portion being tapered in thickness to reduce in thickness in a direction from the scleral portion to the end of the anterior chamber portion.
2. A device according to Claim 1 wherein the transverse cross-sectional shape of the elongate passage has a width the thickness ratio of at least 1.50.
3. A device according to Claim 1 or Claim 2 wherein the tapered end region tapers in thickness, as considered along its length, in a direction which corresponds to the thickness direction of the passage zone.
4. A device according to any one of the preceding claims wherein the anterior chamber portion is tapered over at least 50% of the length of that portion.
5. A device according to any one of the preceding claims wherein the passage zone terminates at a surface which intersects the passage zone obliquely.
6. A device according to any one of the preceding claims wherein the scleral portion is of a constant cross-sectional shape and dimension along substantially the whole of its length.
7. A device according to any one of the preceding claims wherein the passage zone comprises a plurality of discrete passages which extend lengthwise through the body and are substantially parallel with one another.
8. A device according to Claim 7 wherein the passages of a plurality lie substantially co-planar.
9. A device according to Claim 7 or Claim 8 wherein a passage extends rectilinearly between ends of the elongate body.
10. A device according to Claim 7 or Claim 8 wherein a passage extends in a non-rectilinear manner between ends of the elongate body.

9.

11. A device according to any one of the preceding claims wherein the or each drainage passage has a cross-sectional area less than 1.0 sq. mm.
12. A device according to Claim 11 wherein said cross-sectional area is less than 0.5 sq. mm.
13. A device according to any one of the preceding claims wherein the passage or at least some of a plurality of passages of a passage zone incorporate valve means to prevent or restrict flow in a direction from the scleral portion to the anterior chamber portion.
14. A device according to any one of the preceding claims wherein side regions extending lengthwise along the edges of the body of polymeric material are tapered as considered in a plane transverse to the length of the body.
15. A device according to any one of the preceding claims wherein side regions of the body of polymeric material are provided with suture holes.
16. A device according to any one of the preceding claims wherein the passage zone comprises a plurality of discrete passages and passages closest to side regions of the body of polymeric material are of a smaller size than other passages of the plurality or of a different cross-sectional shape.
17. A device according to any one of the preceding claims wherein an outer surface region of the body is provided with auxiliary drainage holes which communicate with said passage zone.
18. A device according to Claim 17 wherein each auxiliary drainage hole has a cross-sectional area which is less than one half the cross-sectional area of the drainage passage with which it communicates.
19. A device according to any one of the preceding claims wherein the anterior chamber portion is provided with an extension zone such that a base portion surface of the anterior chamber portion lies displaced further from the passage zone.
20. A device according to any one of the preceding claims wherein a transverse formation is provided between the anterior chamber and scleral portions.
21. A device according to Claim 20 wherein said transverse formation

10.

comprises a groove.

22. A device according to any one of the preceding claims wherein the material of the flexible elongate body of polymeric material has non-uniform physical properties.

23. A device according to Claim 22 wherein said material is stiffer and/or less resilient at at least the distal end of the anterior chamber portion than at the scleral portion.

24. A device according to Claim 23 or Claim 24 wherein the elongate body incorporates the reinforcing material selectively positioned to provide a non-uniform resistance to bending.

25. A device according to any one of the preceding claims wherein the material of the elongate body is transparent.

26. An ophthalmic drainage device according to Claim 1 and substantially as hereinbefore described.



The
Patent
Office



Application No: GB 9500008.9
Claims searched: 1 to 26

Examiner: Mr S.J.Pilling
Date of search: 18 March 1996

Patents Act 1977
Amended Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK CI (Ed.O): A5R (RCEX, RGEX, RGH, RGEB)

Int CI (Ed.6): A61F 9/00

Other: -

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	WO 94/02081A1	(Wong) Page 3 lines 34 to page 4 line 15, page 8 line 15 to page 9 line 5 and Figure 3.	1,5,6, 11,12, 19
X	WO 91/18568A1	(Wright Medical) Page 3 line 33 to page 4 line 12, page 6 lines 11 to 17, page 7 lines 26 to 29 and Figure 4.	1,5,11, 12,19
X	WO 91/12046A1	(Atos Medical) See the abstract, page 6 lines 28 to 33, page 7 lines 12 to 16.	1,5,6,11 ,12,19
X:Y	US 5300020	(Esperance) Column 1 lines 56 to 67, column 3 lines 33 to 38 and Figures 1 and 5.	X:1,4,6, 11,19, 20 Y:7-9
Y	US 5034176	(Lippman) Column 1 line 22 to column 2 line 43 and Figure 6	7-9
X:Y	US 4037604	(Newkirk) Column 1 lines 26 to 40, column 2 lines 27 to 34 and Figure 1.	X:1,4,5, 11- 13,19, 20 Y:7-9

X Document indicating lack of novelty or inventive step
Y Document indicating lack of inventive step if combined with one or more other documents of same category.

& Member of the same patent family

A Document indicating technological background and/or state of the art.
P Document published on or after the declared priority date but before the filing date of this invention.
E Patent document published on or after, but with priority date earlier than, the filing date of this application.



The
Patent
Office

12

Application No: GB 9500008.9
Claims searched: 1 to 26

Examiner: Mr S.J. Pilling
Date of search: 18 March 1996

Category	Identity of document and relevant passage	Relevant to claims
X:Y	US 3788327 (Donowitz) Column 1 lines 54 to 57, column 2 lines 29 to 41, column 3 lines 19 to 26, column 4 lines 27 to 35, Figures 2 and 4.	X:1,4,5, 11-13, 15, 19, 20 Y:7-9

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

THIS PAGE LEFT BLANK

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☒ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

THIS PAGE LEFT BLANK